

1 HB138
2 156221-1
3 By Representative Todd
4 RFD: Public Safety and Homeland Security
5 First Read: 14-JAN-14
6 PFD: 01/10/2014

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8 SYNOPSIS: Under existing law, a pharmacy operated by a
9 corrections facility or county jail may redispense
10 unused prescription drugs under certain conditions.

11 This bill would provide for the redispensing
12 under certain conditions of unused prescription
13 drugs by pharmacies operated in or on behalf of HIV
14 clinics.

15
16 A BILL
17 TO BE ENTITLED
18 AN ACT

19
20 Relating to the redispensing under certain
21 conditions of unused prescription drugs by pharmacies operated
22 in or on behalf of HIV clinics; to define HIV clinic; and to
23 provide conditions and protocols for the redispensing of
24 unused prescription drugs by HIV clinic pharmacies.

25 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

26 Section 1. (a) As used in this section, the
27 following terms shall have the following meanings:

1 (1) CUSTOMIZED PATIENT MEDICATION PACKAGE. A package
2 that is prepared by a pharmacist for a specific patient and
3 that contains two or more prescribed solid oral dosage forms.

4 (2) HIV CLINIC. Any hospital, nursing home, surgical
5 center, or any other clinic, office, or facility in which
6 medical services are offered or provided to treat individuals
7 infected with human immunodeficiency virus.

8 (3) REPACKAGING. The process by which the pharmacy
9 prepares a prescription it accepts pursuant to this section in
10 a unit-dose package, unit-of-issue package, or customized
11 patient medication package for immediate dispensing in
12 accordance with a current prescription.

13 (4) UNIT-DOSE PACKAGE. A package that contains a
14 single-dose drug with the name, strength, control number, and
15 expiration date of that drug on the label.

16 (5) UNIT-OF-ISSUE PACKAGE. A package that provides
17 multiple doses of the same drug, but each drug is individually
18 separated and includes the name, lot number, and expiration
19 date of the drug.

20 (b) A pharmacy operated by an HIV clinic or operated
21 by a company under contract with an HIV clinic shall accept,
22 for the purpose of redispensing, a prescription drug that has
23 been dispensed and has left the control of the pharmacy or
24 pharmacist if the prescription drug is being returned by the
25 HIV clinic that has met the requirements of routine on-site
26 inspections by the pharmacy or pharmacist and has a registered
27 professional nurse or a licensed practical nurse who is

1 responsible for the security, handling, and administration of
2 prescription drugs within the HIV clinic and if all of the
3 following conditions are met:

4 (1) The pharmacy or pharmacist is satisfied that the
5 conditions under which the prescription drug has been
6 delivered, stored, and handled before and during its return
7 were such as to prevent damage, deterioration, or
8 contamination that would adversely affect the identity,
9 strength, quality, purity, stability, integrity, or
10 effectiveness of the prescription drug.

11 (2) The pharmacist is satisfied that the
12 prescription drug did not leave the control of the registered
13 professional nurse or licensed practical nurse responsible for
14 the security, handling, and administration of that
15 prescription drug and that the prescription drug did not come
16 into the physical possession of the individual for whom it was
17 prescribed.

18 (3) The pharmacist is satisfied that the labeling
19 and packaging of the prescription drug are accurate, have not
20 been altered, defaced, or tampered with, and include the
21 identity, strength, expiration date, and lot number of the
22 prescription drug.

23 (4) The prescription drug was dispensed in a
24 unit-dose package or unit-of-issue package.

25 (c) A pharmacy operated by an HIV clinic or operated
26 by a company under contract with an HIV clinic shall not
27 accept for return prescription drugs as provided pursuant to

1 this section until the pharmacist in charge develops a written
2 set of protocols for accepting, returning to stock,
3 repackaging, labeling, and redispensing prescription drugs.
4 The written protocols shall be maintained on the premises of
5 any pharmacy dispensing prescriptions for the HIV clinic and
6 shall be readily accessible to each pharmacist on duty. The
7 written protocols shall include, at a minimum, each of the
8 following:

9 (1) Methods for ensuring that damage, deterioration,
10 or contamination has not occurred during the delivery,
11 handling, storage, or return of the prescription drugs such
12 that it would adversely affect the identity, strength,
13 quality, purity, stability, integrity, or effectiveness of the
14 prescription drugs or otherwise render the drugs unfit for
15 distribution.

16 (2) Methods for accepting, returning to stock,
17 repackaging, labeling, and redispensing the prescription drugs
18 returned pursuant to this section.

19 (3) A uniform system of recording and tracking
20 prescription drugs that are returned to stock, repackaged,
21 labeled, and redistributed pursuant to this section.

22 (d) If the condition of a prescription drug and its
23 package meets the standards set forth in subsection (c), a
24 prescription drug shall be returned to stock and redistributed
25 as follows:

26 (1) A prescription drug that was originally
27 dispensed in the manufacturer's unit-dose package or

1 unit-of-issue package that is returned in that same package
2 may be returned to stock, repackaged, and redispensed as
3 needed.

4 (2) A prescription drug that is repackaged into a
5 unit-dose package or a unit-of-issue package by the pharmacy,
6 dispensed, and returned to that pharmacy in that unit-dose
7 package or unit-of-issue package may be returned to stock, but
8 it shall not be repackaged. A unit-dose package or
9 unit-of-issue package prepared by the pharmacist and returned
10 to stock shall only be redispensed in that same unit-dose
11 package or unit-of-issue package and shall only be redispensed
12 once. A pharmacist shall not add unit-dose package drugs to a
13 partially used unit-of-issue package.

14 (e) This section does not apply to any of the
15 following:

16 (1) A controlled substance.

17 (2) A prescription drug that is dispensed as part of
18 a customized patient medication package.

19 (3) A prescription drug that is not dispensed as a
20 unit-dose package or a unit-of-issue package.

21 (4) A prescription drug that is not properly labeled
22 with the identity, strength, lot number, and expiration date.

23 Section 2. This act shall become effective on the
24 first day of the third month following its passage and
25 approval by the Governor, or its otherwise becoming law.